JUL - 5 2006

ELEKTA INSTRUMENT AB K061540

Dokumentnamn/*Name of document*
Special 510(k)

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Louise Lindblad	.	1
Avser/*Regarding* Leksell GammaPlan®		Directory

Section 4 - 510(k) Summary

As Required by 21 CFR 807.87(k)510 (k) Summary

1. Subscribers Name & Address

Elekta Instrument AB
Kungstensgatan 18, P:O Box 7593
SE-103 93 Stockholm, Sweden
Tel: (011) 46 8 587 254 00
Fax: (011) 46 8 587 255 00
Contact Person for this submission: Ms Louise Lindblad
Official Correspondent: Mr Peter Löwendahl

2. Trade Name

Leksell GammaPlan®

3. Device Classification

Common Name	Product Code	Class	Regulation Number
Radionuclide radiation therapy system	IWB	II	892.5750

4. Regulatory History (Unmodified Predicate Device)

Devices	510(k) #
GammaPlan®	K051022

5. Other relevant submissions

Devices	510(k) #
Leksell GammaPlan®	K973441

6. Device Description (for detailed description see Section "Device Description")

Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with the Leksell Gamma Knife®. Leksell Gamma Plan® is intended to be used for planning the dosimetry of treatments, in stereotactic radiosurgery and stereotactic radiotherapy.

7. Intended Use

Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with Leksell Gamma Knife®.

8 Substantial Equivalence

The functionality for Leksell GammaPlan® is equivalent to its predicate devices GammaPlan® (K051022) and Leksell GammaPlan® (K973441) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 5 2006

Ms. Louise Lindblad
Elekta Instrument AB
Kungstensgatan18
P.O. Box 7593
Stockholm
SWEDEN SE-103 93

Re: K061540
Trade/Device Name: Leksell GammaPlan®
Regulation Number: 21 CFR §892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: May 30, 2006
Received: June 5, 2006

Dear Ms. Lindblad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section 7- Indications for Use Statement

510(k) Number	To be defined K061540
Device Name	Leksell GammaPlan®
Indications for Use	Leksell GammaPlan® is a computer-based dose planning system specifically designed for use with Leksell Gamma Knife®.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061540